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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/602,823	06/25/2003	Olivier De Lacharriere	016800-515	1993

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Alexandria, VA 22313-1404

EXAMINER

BALLARD, KIMBERLY

ART UNIT	PAPER NUMBER
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1649

MAIL DATE	DELIVERY MODE
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03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/602,823

Applicant(s)

LACHARRIERE ET AL.

Examiner

Kimberly Ballard

Art Unit

1649

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-54 and 64-95 is/are pending in the application.
- 4a) Of the above claim(s) 39, 40, 45, 46 and 64-67 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37, 38, 41-44, 47-54 and 68-95 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Formal Matters

The Examiner of your application in the USPTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Kimberly Ballard, Art Unit 1649.

Status of Application, Amendments, and/or Claims

Claims 37, 43, 44 and 53 have been amended and new claims 68-95 have been added as requested in the amendment filed December 10, 2009. Following the amendment, claims 37-54 and 64-95 are pending in the instant application. Claims 39, 40, 45, 46, and 64-67 have been withdrawn from prosecution. Accordingly, claims **37, 38, 41-44, 47-54, and 68-95** are under examination in the current office action.

Withdrawn Objections or Claim Rejections

The objection to claims 43 and 44, set forth at paragraph 8 of the previous office action (mailed 09/16/2008), is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 43 and 44 under 35 U.S.C. 112, second paragraph, as set forth at paragraphs 19-20 of the previous office action (mailed 09/16/2008), is withdrawn in view of Applicants' amendment to the claims.

The rejection of claims 37, 38, 41-44 and 47-54 under 35 U.S.C. 112, first paragraph (scope of enablement), as set forth at paragraphs 21-25 of the previous office action (mailed 09/16/2008), is withdrawn in view of Applicants' amendments to the claims.

Maintained and New Claim Rejections, Necessitated by Amendment

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The rejection of claims 37, 38, 41-42 and 47-54 under 35 U.S.C. 103(a) as being unpatentable over Robinson and Perkins (*Contact Dermatitis*, 2001; 45:205-213, cited previously) is maintained for reasons of record and for reasons discussed below, and is further applied to amended claims 43 and 44 and new claims 68-80 and 82-95.

Claims 37 and 53 (and depended claims thereof) are directed to a non-therapeutic method of identifying persons having sensitive skin to a capsaicinoid by application of an aqueous or non-aqueous alcoholic solution comprising a stimulant, a capsaicinoid or capsaicin at a concentration of between $1 \times 10^{-6}\%$ and $5 \times 10^{-4}\%$ comprising a physiologically acceptable aqueous alcohol vehicle to a skin area, and deducing information regarding the skin reactivity as a function of the unattractive sensations. Newly added claims 68-80 and 82-95 are drawn to a non-therapeutic method of evaluating the level of skin neurosensitivity of an adult individual to a capsaicinoid, comprising applying to a skin area of the individual a composition comprising an aqueous or aqueous-alcoholic solution and a capsaicinoid or a mustard oil at a concentration of between $1 \times 10^{-6}\%$ and $5 \times 10^{-4}\%$ by weight, recording whether the individual detects or perceives an unattractive sensation, and deducing therefrom information regarding the skin neurosensitivity of the individual. Additional claim limitations recite additional method steps, stimulant concentrations or concentration

gradient increases, skin areas for testing, ethanol percentages, and waiting times between application and assessment.

Robinson et al. teach a method of assessing skin irritation by using 100-10,000 mM capsaicin in 80% ethanol dried onto filter papers, then rehydrated with water and applied onto the forearm of the subjects, and waiting 3 minutes (i.e., 180 seconds) before recording the sensory responses for both treatment and control skin areas (the opposite arm exposed to vehicle served as non-treated control) (see "Materials and Methods" pp. 206-207). The sensory responses perceived by the subjects and used to assess the treatment included stinging, burning, pruritis or itching, hotness, or pins and needles (see pp. 206-207). Robinson et al. further teach that the concentration of capsaicin was increased by a factor between 1 and 10 and application of capsaicin was repeated until a moderate sensory response was elicited, at which concentration no further exposures were performed (see Figure 5, p. 210).

In the response filed December 10, 2008, Applicants' argue that the capsaicin treatment studies in Robinson et al. were performed by using capsaicin in 80% ethanol at concentrations of 100 to 10,000 μM , which is equivalent to $3.12 \times 10^{-3}\%$ to $3.12 \times 10^{-1}\%$ by weight, and which Applicants note is outside the instantly claimed range of present claims 37 and 53 ($1 \times 10^{-6}\%$ to $5 \times 10^{-4}\%$). Applicants assert that there is no indication or suggestion in Robinson et al. that application of capsaicin solutions at concentrations lower than 100 μM would provide predictable results in providing the desired information. Therefore, Applicants argue, one of ordinary skill in the art would have little motivation to modify the teachings of Robinson by lowering the concentration

of the capsaicin solutions to below 100 μ M. Further, Applicants argue that Robinson et al. does not disclose or suggest the use of ethanol with concentration different from 80% would provide predictable results, and thus one of ordinary skill in the art would not be motivated to modify Robinson's teachings to use ethanol concentrations different than 80%, such as 1% to 50%, 5% to 20%, 8% to 15%, and 10% recited in instant claims 48-51.

Applicant's arguments filed December 10, 2008 have been fully considered but they are not persuasive. In response to applicant's argument that there is no suggestion to modify the teachings of Robinson et al., KSR forecloses the argument that a specific teaching, suggestion, or motivation is required to support a finding of obviousness. See the recent Board decision *Ex parte Smith*, --USPQ2d--, slip op. at 20, (Bd. Pat. App. & Interf. June 25, 2007) (citing KSR, 82 USPQ2d at 1396) (available at <http://www.uspto.gov/web/offices/dcom/bpai/prec/fd071925.pdf>). Rather, an additional rationale for the instant finding of obviousness is that the claims would have been obvious because a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. Utilizing one concentration instead of another, for example, amounts to a simple substitution of one known, equivalent element for another to obtain predictable results. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense.

In this case, one of ordinary skill in the art would understand the general principles of optimizing the concentrations of neurostimulants and diluents such as for pharmacological testing. As stated in the previous office action, MPEP § 2144.05 notes

that it is a normal desire for scientists or artisans to improve upon what is already generally known, and this provides the motivation to determine the optimum combination of percentages for achieving a desired effect. In other words, optimization of parameters is a routine practice that would be obvious for a person of ordinary skill in the art to employ. The skilled artisan, for instance, would have recognized that detection of capsaicin sensations is possible below the lowest capsaicin concentration (100 μ M) taught Robinson et al. As demonstrated in Figure 5 (p. 210), the 100 μ M concentration of capsaicin was recorded as a *moderate* response for some of the individuals in the study, indicating that the minimum detection level for capsaicin would be lower still, particularly if it were to be applied to even more sensitive areas such as on the face. Moreover, there is no evidence of record to indicate that the claimed concentrations of capsaicin or ethanol are critical to the invention. Thus, absent some demonstration of unexpected results from the claimed parameters, this optimization would have been obvious at the time of applicants' invention. Accordingly, the teachings of Robinson et al. render obvious the present invention of claims 37, 38, 41-44, 47-54, 68-80 and 82-95.

Claim 81 is rejected under 35 U.S.C. 103(a) as being unpatentable over Robinson and Perkins (*Contact Dermatitis*, 2001; 45:205-213, cited previously) as applied to claims 37, 38, 41-44, 47-54, 68-80 and 82-95 above, and further in view of Seidenari et al. (*Contact Dermatitis*, 1998; 38(6):311-315, abstract only).

The teachings of Robinson et al. are discussed above. While Robinson et al. teaches the application of stimulant to the forearm and cheek for assessment of skin sensitivity, the reference does not explicitly teach application to the wing of the nose as recited in instant claim 81.

Seidenari et al. note that the stinging test, which is widely accepted as a marker of sensitivity and employed for the selection of subjects having sensitive skin, is performed by applying an irritant to the nasolabial fold (i.e., the wing of the nose) and evaluating the intensity of subjective symptoms (see abstract).

Thus, it would have been obvious to one of skill in the art at the time the invention was filed to modify the skin sensitivity assessment method taught by Robinson et al. by applying the stimulant/irritant (in this case, capsaicin) to the nasolabial fold of the individual being tested. This is because the artisan has good reason to pursue the known options within his or her technical grasp to obtain predictable results. Such would amount to substitution of known equivalent elements, i.e. skin area for another, to yield predictable results.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 37, 38, 41-44, 47-54, as amended, and new claims 68-95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly

point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claims 37, 53, 68, 70, 78, 87 and 92 each recite a non-therapeutic method for identifying persons having sensitive skin to a capsaicinoid (or evaluating the level of skin neurosensitivity of an individual to a capsaicinoid), wherein a peripheral nervous system stimulant that is a capsaicinoid or a mustard oil is applied to the skin of the individual. As the claims are written, it would appear that sensitivity to a capsaicinoid can be determined by application of a mustard oil. However, both the relevant art and Applicant acknowledge that mustard oil is *not* a capsaicinoid (see, in particular, paragraph 0053 of the instant specification and page 19 of Applicants' response filed 03/14/2007, indicating that "[t]hese specific compounds have particular structures.") Therefore, it is unclear how skin sensitivity to a capsaicinoid can be assessed using the peripheral nervous system stimulant of a mustard oil. Dependent claims 38, 41-44, 47-52, 54, 69, 71-77, 79-86, 88-91 and 93-95 are included in this rejection because they do not remedy the situation and include all limitations of the independent claims from which they depend.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Ballard whose telephone number is 571-272-2150. The examiner can normally be reached on Monday-Friday 9 AM - 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker can be reached on 571-272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kimberly Ballard, Ph.D.
Art Unit 1649

/Elizabeth C. Kemmerer/
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